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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/511,481   | 02/23/2000  | Gary J. Becker       | 97-998 US - DIV.    | 3875             |
| 7470   | 7590        | 02/10/2004           | EXAMINER            |                  |
| WHITE & CASE LLP<br>PATENT DEPARTMENT<br>1155 AVENUE OF THE AMERICAS<br>NEW YORK, NY 10036 |             |                      | CHATTOPADHYAY, URMI |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 3738                | 18               |

DATE MAILED: 02/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                 |                 |
|------------------------------|-----------------|-----------------|
| <b>Office Action Summary</b> | Application No. | Applicant(s)    |
|                              | 09/511,481      | BECKER, GARY J. |
| Examiner                     | Art Unit        |                 |
| Urmie Chattopadhyay          | 3738            | PR              |

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 05 January 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 21-29, 31-62 and 71-79 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 37-46, 62 and 71-79 is/are allowed.
- 6) Claim(s) 21-23, 26-29, 31-36 and 47-61 is/are rejected.
- 7) Claim(s) 24 and 25 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 05 January 2004 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. 09/094,402.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                     | Paper No(s)/Mail Date. _____ .  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____ .                                  |

## **DETAILED ACTION**

### *Request for Continued Examination*

1. The request filed on 1/5/04 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on Application No. 09/511,481 is acceptable and a RCE has been established. An action on the RCE follows.

### *Response to Amendment*

2. The amendment filed 1/5/04 has been entered as Paper No. 17. The changes made to the figures, specification and claims have been approved by the examiner. Claims 30, second 62 and 63-70 have been canceled, and new claims 71-79 have been added. All the pending claims, claims 21-29, 31-62 and 71-79, are being considered for further examination on the merits.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 47-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Moriuchi (USPN 6,013,854, as cited in last office action).

Moriuchi discloses a stent with all the elements of claim 47. See Figures 5 and 6 for a plurality of filament segments arranged to form a first repetitious pattern comprised of peaks and valleys and that advances substantially helically along the longitudinal axis. Figure 6 clearly shows a plurality of connecting segments (111) connecting peaks to valleys. See columns 3-4, lines 62-10 for the connecting segments and the peaks and valleys they connect being comprised of a continuous piece of material.

Claims 48 and 49, see Figure 6 for the peaks and valleys being of curvilinear filaments, and at least a portion of the first repetitious pattern being *generally* sinusoidal.

Claims 50-53, see Figure 6 for non-contiguous staggered connecting elements (111) forming a second repetitious helical pattern.

Claim 54 is a product-by-process claim, and according to MPEP § 2113, this claim is not limited to the manipulations of the recited steps, only the structure implied by the steps. The patentability of a product does not depend on its method of production, but on the product itself. See columns 3-4, lines 62-10.

#### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 21-23, 26-29, 31-36 and 55-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogi et al. (USPN 5,925,061, as cited in last office action) in view of Moriuchi.

Ogi et al. discloses a stent with all the elements of claims 21, 35 and 55, but is silent to the stent comprising a second helically propagating segment, wherein the first and second segments are joined together by connecting members/struts. See Figure 7 and column 9, lines 11-15 for a body located between first and second square-like tubular ends. See Figure 1 for a helically propagating first segment having repetitious pattern of peaks (15p) and valleys (15v) joined together by integral (column 2, lines 32-44) connecting member/struts (18). A peak is connected only to first and second filament portions and a valley is connected to only second and third filament portions. The peak and valley have substantially the same width. Moriuchi teaches a stent with a second helically propagating segment parallel and joined to a first helically propagating segment by connector members/struts (111). See Figures 5 and 6. "By forming the helix structure of two parallel wires, it becomes possible to make the angle  $\alpha$  of the helix to the direction of the axis of the stent smaller than the corresponding angle  $\beta$  for the helix structure formed of a single wire ( $\alpha < \beta$ ) as shown in FIGS. 9(a) and (b). As the result, the stent can be made more flexible. The number of wires disposed parallel with each other may be greater than 2, for example, 3 or 4". See column 12, lines 15-24. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Moriuchi to modify the single helical segment stent of Ogi et al. by including at least a second parallel (claim 23), helically propagating segment to the stent structure and joining first and second segments with the connecting members/strut (18) in order to achieve a smaller helical angle that makes the stent more flexible.

Claim 22, see column 3, lines 15-18 for different pitches.

Claims 26-27, see column 6, lines 8-19 for self-expanding and plastically deformable materials.

Claims 28 and 29, see Figure 1 for a circumferential dimension being parallel to the circumference of the stent and segment lengths being longer than the length of the body.

Claims 31-32 are product-by-process claims, and according to MPEP § 2113, these claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. The patentability of a product does not depend on its method of production, but on the product itself. See column 5, lines 45-60.

Claim 33, see Figure 7 for first segment having varying amplitude.

Claim 34, see Figure 7 for pattern being generally sinusoidal.

Claim 36, see Figure 1 for a circumferential dimension being parallel to the circumference of the stent and an expanding circumferential dimension when the stent is expanded.

With respect to claim 55, because first and second helical segments will be connected by connecting elements (18), the midpoints of at least three connecting elements will form a first imaginary helical line substantially parallel to a second imaginary helical line formed by a second set of at least three connecting elements (can generally be seen in Figure 3 if it included the second helical segment).

Claims 56-61, see Figure 1 for required filament portions limitations.

***Allowable Subject Matter***

7. Claims 37-46, 62 and 71-79 are allowed.
8. Claims 24 and 25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

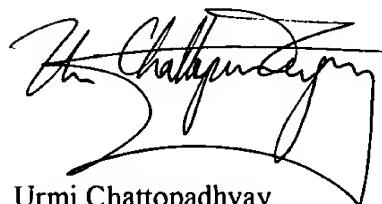
9. Applicant's arguments, see page 35, line 1 to page 36, line 10, filed 1/5/04, with respect to the rejection(s) of claim(s) 21-23, 26-46 and 55-61 under 102(e) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made under 103(a) by Ogi in view of Moriuchi, as set forth supra.
10. Applicant's arguments filed 1/5/04, with respect to the rejection of claims 47-54 under 102(e) by Moriuchi, have been fully considered but they are not persuasive.
11. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the helical element is curved and undulating) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).
12. Applicant argues that the Moriuchi stent does not have the "connecting segments connecting proximal portions of the first helically advancing pattern to the distal portions of the... pattern" recited in the rejected instant claims. The examiner disagrees. The two wires

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102a and 102b have a junction point (111) therebetween that provides as a connecting member, as shown in Figure 6. It is not required that the connecting segments have an extended length between the helical segments. In fact, the junction (111) provides as a connecting segment comparable to that shown in applicant's Figure 3A.

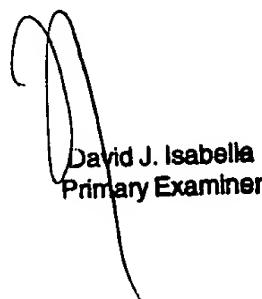
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmie Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 872-9306. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmie Chattopadhyay

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David J. Isabella  
Primary Examiner